K003056

DEC 13 2000

510(k) Summary of Safety and Effectiveness

Submitted By:

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Germany
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Date 2000-08-29

Device:

Trade Name: Ovarial Biopsy Set /Ovarial Biopsy Needle
Proposed Classification Name: Assisted Reproduction Needles
Class II 85 MQE

Predicate Device:

Trade name:	**Class**	**CFR Referece**	**Procode**
Ovum Pick-Up Aspiration Needle	II	884.6100	85 MQE

Classification name: Assisted reproduction needles

Manufacturer: Cook Ob/Gyn
1100 West Morgan Street
Spencer, IN 47460

510(k) reference number: K983593

Device description:
The Ovarial Biopsy Sets / Needles are used for transvaginal ultrasound guided aspiration and flushing of oocytes from ovarian follicles. The Sets are sterile packed intended for one time use.

Substantial Equivalence:
These devices will be manufactured according to specified controls and a Quality Assurance Program. These devices will undergo packaging nearly similar to the devices marketed by Cook OB/Gyn. Materials and physical construction are nearly similar to predicate devices, too. Being similar with respect to the indications for use to predicate devices, these devices meet the requirements for section 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Angelika Albrecht
Safety Officer for Medical Devices
Labotect GmbH
Labor-Technik-Göttingen
Willi-Eichler-Straße 25
D-37079 Göttingen
GERMANY

DEC 13 2000

Re: K003056
Ovarial Biopsy Set 1-324102-324108; Ovarial Biopsy Set 2-324200-324202; Ovarian Biopsy Needle – 322128; Assisted Reproduction Needles
Dated: September 28, 2000
Received: October 2, 2000
Regulatory Class: II
21CFR §884.6100/Procode: 85 MQE

Dear Ms. Albrecht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003056

Device Name: Ovarial Biopsy Set / Ovarial Biopsy Needle

Indications For Use:

The Ovarial Biopsy Set / Needle is used for aspiration and flushing of oocytes from ovarian follicles.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003056